



Pharmacia & Upjohn

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Global Regulatory Affairs
David W. Johnson
Global Promotion & Labeling
0632-298-130
Telephone No. (616) 833-4395
Facsimile No. (616) 833-8632

May 10, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Subject: Comments on Draft Guidance for Industry on Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling [Docket No. 99D-0254]

To whom it may concern;

Pharmacia & Upjohn would like to make the following comments and suggestions in response to the Notice announcing availability of the subject guidance published in the Federal Register on March 12, 1999.

1. It is common practice for a pharmaceutical company to develop a logo that contains both the proprietary and established names along with graphic material designed to create brand recognition when a new pharmaceutical product is launched into the US market. Since publication of the original guidance in April 1994, logos for a variety of new products have been introduced and are now well recognized within the marketplace as an integral part of the brand that they were designed to represent. Efforts to change a logo without appropriate planning and testing can have a negative impact on brand recognition and promotional activities for an established product. Consequently, we suggest that it be made clear in either the preamble or introduction that this guidance will be applied only to new advertising and promotional materials submitted to FDA after publication of the final guidance document.
2. The statement in section IIA of the draft: "intervening matter that in any way would detract, obfuscate, or de-emphasize the established name", is open to a wide range of interpretations. For example, this statement could be interpreted to mean that an icon, graphic material or other trademark placed directly to the right of the proprietary name could be considered intervening when the established name appears directly under the proprietary name. The natural tendency to read from left to right draws

attention to the icon or graphic material immediately to the right of the proprietary name before moving on to the next line where the established name appears. In our opinion, placing an icon, graphic material or another trademark immediately to the right of the proprietary name does not detract, obfuscate, or de-emphasize the established name when it is prominently displayed immediately underneath the proprietary name. To help avoid any misinterpretation of this statement, we suggest that the final guidance include examples of acceptable formats for displaying the proprietary and established names. These examples should include, but not be limited to the following.

Product A (brand of any drug)

Product A
(brand of any drug)

Icon Product A
(brand of any drug)

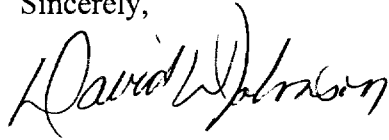
Product A Icon
(brand of any drug)

“Product A” represents the proprietary name and “any drug” represents the established name. Use of parentheses and the phrase “brand of” are optional in all of the above examples.

3. While section IIB of the draft guidance regarding size of the proprietary and established names has not changed significantly from the original guidance, we believe that the example included for the purpose of providing additional clarification actually creates the potential for more confusion and misinterpretation. Specifically, it is not completely clear what is meant by: “The size of the established name letters should be independent of whether the established name is printed in upper- or lower-case letters”. To help avoid any misinterpretation of this section, we suggest adding specific examples in the final guidance to describe how the size requirements for the established name may be applied in actual practice. These examples should include, but not be limited to the following.
 - When the proprietary name is printed in all upper case letters of the same height and the established name is printed in all lower case letters, the tallest ascending or descending letter in the established name, such as t or g, should be at least half the height of the letters in the proprietary name.
 - When either or both the proprietary and established names are printed in mixed case, the tallest ascending or descending letter in the established name, such as t or g, should be at least half the height of the tallest letter in the proprietary name. Similarly, the shortest letter in the established name, such as e or o, should be at least half the height of the shortest letter in the proprietary name.

We appreciate the opportunity to comment on the draft guidance and hope that the suggestions outlined above will provide useful input during development of the final guidance document.

Sincerely,

A handwritten signature in black ink, appearing to read "David W. Johnson". The signature is fluid and cursive, with the first name "David" being the most prominent.

David W. Johnson
Promotion Review Manager
Global Promotion & Labeling

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